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US006284471B1

(12) **United States Patent**  
**Le et al.**(10) Patent No.: **US 6,284,471 B1**  
(45) Date of Patent: **Sep. 4, 2001**(54) **ANTI-TNFA ANTIBODIES AND ASSAYS  
EMPLOYING ANTI-TNFA ANTIBODIES**

WO92/11383 9/1992 (WO).

**OTHER PUBLICATIONS**(75) Inventors: **Junming Le**, Jackson Heights; **Jan Vilcek**, New York, both of NY (US);  
**Peter Dadonna**, Palo Alto, CA (US);  
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**Scott A. Siegel**, Westborough, MA (US)N. Sites, DP. et al (ed.) Medical Immunology, Appleton & Lange, p. 101, 1997.\*  
Moller et al., Cytokine 2: 162-9, 1990.\*  
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CA AN CA 118(S):37840n, Le et al., WO9216553A1, Oct. 1992,, 105pp.\*(73) Assignees: **New York University Medical Center**, New York, NY (US); **Centocor, Inc.**, Malvern, PA (US)Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," *Nature*, 316:552-554 (1985).

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," *Science*, 229:869-871 (1985).(21) Appl. No.: **08/192,093**Morrison, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," *Science*, 229:1202-1207 (1985).(22) Filed: **Feb. 4, 1994**Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," *Biochem. & Biophys. Res. Comm.*, 137 (2):847-854 (1986).**Related U.S. Application Data**Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," *J. of Immun. Methods*, 96:57-62 (1987).(63) Continuation-in-part of application No. 08/010,406, filed on Jan. 29, 1993, now abandoned, and a continuation-in-part of application No. 08/013,413, filed on Feb. 2, 1993, now abandoned, which is a continuation-in-part of application No. 07/943,852, filed on Sep. 11, 1992, now abandoned, which is a continuation-in-part of application No. 07/853,606, filed on Mar. 18, 1992, now abandoned, which is a continuation-in-part of application No. 07/670,827, filed on Mar. 18, 1991, now abandoned.Piguet, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," *J. Exp. Med.*, 166:1280-1289 (1987).(51) Int. Cl.<sup>7</sup> ..... **C07K 16/24; A61K 39/395; C12N 15/00; G01N 33/53**Meager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," *Hybridoma*, 6 (3):305-311 (1987).(52) U.S. Cl. .... **435/7.1; 435/69.6; 435/70.21; 530/387.3; 530/388.23; 530/391.3; 424/133.1; 424/139.1; 424/141.1**Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," *Hybridoma*, 6 (4):359-370 (1987).(58) Field of Search ..... **530/387.3, 388.23, 530/391.3; 435/7.1, 240.27, 172.2, 70.21**Bringman, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," *Hybridoma*, 6 (5):489-507 (1987).(56) **References Cited****U.S. PATENT DOCUMENTS**4,603,106 7/1986 Cerami et al. .  
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WO92/13095 8/1992 (WO) .**Primary Examiner**—Anthony C. Caputa**Assistant Examiner**—Karen A. Canella(74) **Attorney, Agent, or Firm**—Hamilton, Brook, Smith & Reynolds, P.C.(57) **ABSTRACT**

Anti-TNF antibodies and anti-TNF peptides, specific for tumor necrosis factor (TNF) are useful for in vivo diagnosis and therapy of a number of TNF-mediated pathologies and conditions, as well as polynucleotides coding for anti-TNF murine and chimeric antibodies, peptides, methods of making and using the antibody or peptides in immunoassays and immuno-therapeutic approaches are provided, where the anti-TNF peptide is selected from a soluble portion of TNF receptor, an anti-TNF antibody or structural analog thereof.

**9 Claims, 36 Drawing Sheets**